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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,847	10/08/2004	Alessandra Mazzeo	1673.01	5846
21901	7590	01/17/2008	EXAMINER	
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			01/17/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/711,847	<b>Applicant(s)</b> MAZZEO ET AL.	
	<b>Examiner</b> Melanie Yu	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>12/9</u>  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application           |
| Paper No(s)/Mail Date _____  | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> |

Continuation of Attachment(s) 6). Other: proposed amendment for allowance.

### **DETAILED ACTION**

1. Applicant's amendments and arguments filed 11 October 2007 have been entered. Claims 5, 7, 8, 10 and 11 have been rejoined with the examined claims.

#### ***Claim Objections***

1. Claims 3-14 are objected to because of the following informalities: claim 3 recites the phrase "constituted by" which is not consistent with appropriate transitional claim language, the phrase should be changed to "comprising". Claim 2 also recites the rod introduced directly into an entire sample. However, the claim should be clarified by stating that the rod comprising the adsorbent cylinders is capable of being inserted into the test tube to provide the sample introduction. Appropriate correction is required.

Claims 6, 9 and 12-14 recite the phrase "characterized by the fact that", which is not consistent with proper transitional language. The phrase should be changed to "wherein". Appropriate correction is required.

With respect to claims 6-9 the term "receives" should be changed to supports.

New claim 14 appears to be the same as new claim 12 and should be canceled.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 3-14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites that the support with the rod with the adsorbent cylinders is positioned above a microplate furnished with microwells. However, it is unclear whether the microplate with microwells is intended to be part of the device or whether only the support with the rods is intended to be the device.

***Interview Summary***

2. Applicant's representative was contacted on 9 December 2007 regarding the issues under 35 USC 112, second paragraph, however no agreement was reached. See the attached proposed amendment for allowance for the corrections required in order to place the claims in condition for allowance.

***Allowable Subject Matter***

3. Claims 3-14 would be allowable if rewritten or amended to overcome the objections and rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. The prior art fails to teach a rod comprising adsorbent cylinders, wherein the rod and adsorbent cylinders are capable of being inserted into a test tube. Hubscher et al. teach small adsorbent cylinders on a rod and connected to a support but the adsorbent cylinders taught by Hubscher et al. extend from the rod at a distance that would render the rod incapable of being inserted into a test tube. The cylinders of Hubscher et al. extend from the rod at a distance of 3.375 inches (col. 7, lines 27-30). One having ordinary skill in the art would recognize that a "large" test tube has a diameter significantly smaller than the distance of the cylinders extending from the rod of Hubscher et al. Kawashima et al. (US 4,025,391) teach a large test tube having a diameter of 5 cm (almost 2 inches) at column 3, lines 33-37. Terasawa et al. (US 4,912,043) teach a large test tube having a diameter of 24 mm (almost 1 inch) at column 5, lines 38-40. The test tube diameters taught by these two references are commonly accepted for "large" test tubes, and therefore the 3.375 inch length cylinders attached to the rod of Hubscher et al. would not be capable of fitting into even a large test tube in the prior art.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Melanie Yu  
Patent Examiner  
Art Unit 1641



LONG V. LE 12/21/07  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Proposed Amendment for Allowance – 10/711,847

1. (cancelled)
2. (cancelled)
3. An assay device for simultaneously detecting different antibodies and antigens via immunoenzymatic tests and ELISA – Enzyme Linked ImmunoSorbent Assay, the device comprising:
  - adsorbent cylinders on which immunocomplexes form;
  - a rod bearing the adsorbent cylinders at positions which protrude a distance from the rod, wherein the rod bearing the cylinders thereon is able to be inserted into a test tube containing a sample so that the samples can be directly introduced to the cylinders;
  - a label positioned on the rod to identify the sample collected in the test tube;
  - a support for carrying a plurality of the rods bearing the cylinders;
  - a microplate having a plurality of wells filled with an ELISA reagent, wherein the wells are positioned at modular distances and the positions of the adsorbent cylinders on the rod correspond to the plurality of wells at the modular distances and the adsorbent cylinders penetrate into the wells when the support is positioned above the microplate.
4. A device according to claim 3, wherein the support is a grill formed of at least two parallel horizontal sides and of at least two vertical parallel sides, the grill has a handle for transport and lifting, and a plurality of notches on the horizontal and vertical sides for situating the rods.

5. (Rejoined) A device according to claim 4, wherein the grill supports twelve rods, and each of the rods bears eight adsorbent cylinders and the microplate comprises ninety-six wells positioned in an array of twelve columns by eight lines at the modular distances.

6. A device according to claim 4, wherein the grill supports eight rods and each of the rods bears twelve adsorbent cylinders, the grill is positioned symmetrically above the microplate, and the microplate comprises ninety-six wells arranged in twelve columns and eight lines at the modular distances.

7. (Rejoined) A device according to claim 4, wherein the grill supports twenty-four rods each of the rods bearing four cylinders, the rods are arranged symmetrically on the grill and the grill is positioned symmetrically above the microplate, wherein the microplate comprises ninety-six wells arranged in twelve columns and eight lines at the modular distances.

8. (Rejoined) A device according to claim 4, wherein the grill supports sixteen rods arranged symmetrically each bearing six cylinders, the rods are arranged symmetrically on the grill, and the grill is positioned above the microplate, wherein the microplate comprises ninety-six wells arranged in twelve columns and eight lines at the modular distances.

9. A device according to claim 3, wherein the microplate is a microstrip comprising twelve wells.

10. A device according to claim 3, wherein the rod bearing the cylinders comprises a place to position a card bearing the identification code of the sample, wherein the card can be removed and inserted into a specific holder on a cover or lid for the test tube comprising a sample and the cover or lid also comprises an external site for the card.



11. A device according to claims 3 and 9, wherein the rods, small cylinders, test tubes and microstrip are constructed entirely for carrying out the test in the field or in non-specialist surgeries or laboratories.

12. A device according to claim 3, wherein each adsorbent cylinder of the device is sensitized with a different antigen for antibody detection assay or with a different antibody for antigen detection assay, with the exception of one adsorbent cylinder that is not sensitized.

13. A device according to claim 3, wherein each adsorbent cylinder of the device is sensitized with a different antibody for antigen detection assay, with the exception of one adsorbent cylinder that is not sensitized.

14. (cancelled)